REMARKS

Claims 1 to 34 are pending. Claims 16 and 32-33 have been cancelled. Claims 35-46 have been withdrawn. Claims 47-53 have been added. Claims 1, 5, 6, and 17 have been amended. Claims 1 and 47 are supported by disclosure in Table C, pages 18-19 of the specification. Claims 5-6 are supported by disclosure on page 3, lines 13-15 of the specification. Claims 17, 52 and 53 are supported by disclosure on page 3, lines 1-7, and on page 20, lines 18-30 of the specification. Claims 48-50 are supported by disclosure on page 1, lines 21-24 of the specification. Claim 51 is supported by disclosure on page 2, lines 18-19, of the specification.

No new matter has been added by this amendment.

The specification has been amended to clarify priority claim.

A petition to correct inventorship is concurrently filed.

35 U.S.C. § 103

Claims 1-4, 8-14, 16-20 and 24-33 were rejected for obviousness over U.S. Patent 6,103,756 ("Gorsek"), in view of Narsing Rao and Guey-Shang Wu, Free Radical Mediated Photoreceptor Damage in Uveitis, 19 Prog. Retinal Eye Res. 41 (2000) ("Rao"), and Gisela Velez and Scott Whitcup, New Developments in Sustained Release Drug Delivery for the Treatment of Intraocular Disease, 83 Br. J. Ophthalmol. 1225 (1999) ("Velez"). The Examiner stated:

> It would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to have used the composition of Gorsek in the treatment of macular degeneration as well as ocular inflammation as suggested by Rao. One having ordinary skill in the art would have been motivated to do so because of Rao's suggestion that antioxidants may effectively treat ocular inflammation caused in part by free radical damage, and the fact that Gorsek discloses the usefulness of the composition therein described in protecting against the damage caused by free radicals through their neutralization. Furthermore, it would have been prima facie obvious for one having ordinary skill in the art at the time of the instant invention to have modified the composition of Gorsek for topical ophthalmic administration. One having ordinary skill in the art would have been motivated to do so given the teaching of Velez that topical administration of ocular therapeutics avoids problems associated by the systemic administration of ocular therapeutics.

Independent claim 1 has been amended to require that the composition is administered orally in amounts within specified daily dosage ranges. Neither Gorsek nor secondary references Rao or Velez describe or suggest the dosage regimen now required by the amended claim 1 and those claims that depend therefrom.

Independent claim 17 has been amended to require identification of a subject suffering from or at risk of developing dry eye or macular degeneration by detecting an elevated level of C-reactive protein. Since neither Gorsek, nor any of the other cited references describes identification of subjects to be treated in this manner, claim 17 and those claims which depend from it are non-obvious over this combination of references.

Claims 1-14, and 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek as modified by Rao and Velez as applied to claims 1-4, 8-14, 16-20, and 24-33 above, and further in view of U.S. Patent Application Publication 2002/0095000 (hereinafter "Troyer"). Regarding this ground of rejection, the Examiner states:

> Gorsek as modified by Rao and Velez, above, describes the treatment of ocular inflammation or macular degeneration using an antioxidant composition, but does not include omega-3 fatty acids such as DHA or omega 3-fatty acids in the composition.
>
> Troyer describes a composition containing blackcurrant seed oil, a source of both omega-3 and omega-6 fatty acids, as well as cod liver oil, a source of omega-3 fatty acid DHA, for promotion of ocular health and treatment of dry eye syndrome.
>
> It would be prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the omega-3 and omega-6 fatty acid composition of Troyer with the composition of Gorsek as modified by Rao and Velez to arrive at the composition of the instant claims. One of ordinary skill in the art would have been motivated to do so because both compositions are directed to the treatment of ocular diseases and the promotion of ocular health, and it is prima facie obvious to combine two elements known by the art as useful for the same purpose to achieve a third element for achieving the exact same purpose.

As is discussed above, independent claims 1 and 17 have been amended. Applicant submits that the amended claims are novel and non-obvious over the combination of Gorsek in view of Rao and Velez. Troyer was cited for the description of the use of omega-3 and omega-6 fatty acids. However, Troyer fails to contribute disclosure pertaining to the daily dosage range requirement of amended claim 1 and the patient selection criterion of amended claim 17. In view of the foregoing claim amendments, this rejection should be withdrawn.

Claims 1-4, 8-20, and 24-34 were rejected for obviousness over Gorsek as modified by Rao and Velez as applied to claims 1-4, 8-14, 16-20, and 24-33 above, and further in view of U.S. Patent 6,365,622 ("Cavazza"). In support of this rejection, the Examiner stated:

> It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the L-carnitine of Cavazza with the composition of Gorsek as modified by Rao and Velez to arrive at the composition of the instant claims. One of ordinary skill in the art would have been motivated to do so because both compositions are directed to the treatment of ocular diseases and the promotion of ocular health, and it is prima facie obvious to combine two elements known by the art as useful for the same purpose to achieve a third element for achieving the exact same purpose.

The claims have been amended to distinguish over the prior art. Gorsek as modified by Rao and Velez fail to describe the dosage requirements of claim 1. Nor do these references describe detection of elevated levels of C-reactive protein to identify subjects to which the anti-inflammatory compositions are to be administered as now required by claim 17. The Cavazza reference was relied upon solely for its description of L-carnitine as an antioxidant. However, the Cavazza reference fails to describe or suggest the use of L-carnitine for alleviating dry eye or macular degeneration. Instead, this reference relates to

> a composition for the prevention and/or treatment of tissular diseases brought about by the presence of free radicals due to environmental pollution; brain or myocardial damages induced by free radicals following cerebral or myocardial ischaemia and attendant riperfusion; of the toxic or diabetic neuropathies and of metabolic disorders in the glucose utilization. (Col. 1, lines 6-12, of Cavazza)

Ocular disorders are mentioned only three times throughout the reference, and in each case, the description of the disorder and context of the description fails to suggest L-carnitine to treat dry eye or macular degeneration. For example, in column 3, lines 10-12, Cavazza describes using α-lipoic acid to treat diabetes-associated disorders such as "neuropathies and ocular cataracts" or "retinal ischemia" (a complication related to Advanced Glycosylation End Products; column 3, lines 32-35). In column 6, lines 17-22, Cavazza describes the relationship between diabetic hyperglycaemia, "ocular or peripheral nervous diseases", and sorbitol content in ocular lens. Moreover, this reference does not provide any description or suggestion of the dosage ranges now claimed in claim 1, nor does it contribute any disclosure relating to detection of C-reactive

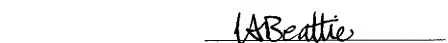
protein to identify subjects suffering from or at risk of developing macular degeneration. Therefore, the amended claims are non-obvious over these references.

CONCLUSION

If there are any questions, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

The Commissioner is hereby authorized to credit any overpayment or charge any deficiencies to Deposit Account No. 50-0311 (Reference No. 21534-002CIP NATL).

Respectfully submitted,



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